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jc690 U.S. PTO
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Express Mail
Label No: **EK530291760**
Date of Deposit: February 28, 2000

TRANSMITTAL OF CONTINUING APPLICATION

jc511 U.S. PTO
09/514759
02/28/00

Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Sir:

This application is a [ ] continuation [ ] divisional
[x] continuation-in-part application filed under the procedure set forth in 37 CFR 1.53(b).

1. PRIOR APPLICATION DATA

Application No: 08/945,497 Filing Date: October 24, 1997

Title: SURGICAL GRIPPING DEVICE

Applicants: John Vivian WOOD
David Malcolm GRANT
Sarah Margaret GREEN
Timothy BENHAM
David GARLICK

2. ENCLOSED ARE:

- [x] Fee Transmittal Form (in duplicate)
- [x] 6 pages description, 2 page(s) claims, 1 page abstract [Total Pages: 9]
- [x] 1 sheet(s) drawings
- [ ] Declaration for Patent Application
  - [ ] Newly executed
  - [ ] Copy from prior application
- [ ] An assignment and recordation cover sheet
- [ ] Small entity status: verified statement that this is a filing by a small entity under 37 C.F.R. 1.9 and 1.27.
- [ ] Preliminary Amendment
- [ ] Information Disclosure Statement

3. [ ] Cancel in this application original claims _____ before calculating the filing fee.

4. [ ] This divisional or continuation application is filed by fewer than all of the inventors named in the prior application and this application is accompanied by a statement requesting deletion of the name(s) of the person(s) who is(are) not inventor(s) in this application.

5. [ ] The [ ] inventorship, [ ] inventor's citizenship, residence or post office address as shown on the original oath or

declaration was changed and approved during prosecution of the prior application, which changes are shown on the enclosed Inventor(s) Information Sheet.

6. [x] Priority of Application No. 9508328.3 filed on April 25, 1995 in United Kingdom is claimed under 35 USC 119.

[ ] A certified copy of the priority application has been filed in prior Application No. _____ filed _____.

7. [ ] The prior application is assigned of record to _____. (For divisional or continuation only; not for CIP.)

8. [x] A petition and fee for three months' extension of time to respond to the Office Action mailed August 27, 1999 in the prior application, until February 27, 2000, has been filed, and a copy of the petition is attached.

9. [ ] A verified statement claiming small entity status has been filed in prior Application No._____ filed _____. A copy of the verified statement is enclosed. Status as a small entity is still proper and is desired.

10. [x] Address all future communications to the correspondence address associated with Customer No. 007812.

By _____
John Smith-Hill, Reg. No. 27,730
[x] Attorney or Agent of Record
[ ] Filed under 37 CFR 1.34(a)

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FEE TRANSMITTAL FORM

Continuation-in-Part Application
based on prior U.S. Application No. 08/945,497

CLAIMS PENDING IN CONTINUATION/DIVISIONAL APPLICATION						
	No. Filed		No. Extra	Rate		Fee
TOTAL CLAIMS	14 - 20	=	0	X $ 18	=	0
INDEP. CLAIMS	1 - 3	=	0	X $ 78	=	0
Additional Multiple Dependent Claim Fee				$260	=	0
				BASIC FILING FEE	=	$690
				Discount for Small Entity	=	0
				TOTAL FILING FEE	=	$690

[x] A check in the amount of $690 is enclosed.

[x] Please charge any additional filing fees under 37 CFR 1.16 which may be required by this paper, or credit any overpayment to Deposit Account No. 19-2560. This sheet is filed in duplicate.

Penelope Stockwell

Penelope Stockwell

February 28, 2000

Date

A Biocompatible Gripping Device

The present invention relates to biocompatible gripping devices for surgical use. More particularly, but not exclusively it relates to biocompatible surgical needle holders having deformable gripping surfaces.

Surgical needle holders, generally in the nature of forceps, are known and used in both general and laparoscopic surgery. Conventionally, the gripping surface or surfaces of such holders are machined to a knurled finish or coated with a relatively hard and rough coating, for example tungsten carbide, to stop the needle from moving or from dropping out of the needle holder during an operation. Gripping surface of this nature tend to distort the needle and may remove a surface coating from the needle as well as removing part of the needle material itself, which is commonly a type of stainless steel. This distortion and degradation of the needle causes problems, particularly in accurate surgical work. Moreover, it is known occasionally for the needle to be pulled out of the holder during surgery, or to twist within the holder resulting in incorrect alignment of a curved needle.

The present invention seeks to mitigate or obviate these or other disadvantages of the prior art.

According to the invention there is provided a biocompatible gripping device for surgical use including at least one deformable gripping surface.

According to another aspect of this invention there is provided a biocompatible gripping device for surgical use, the device comprising gripping means having at least one deformable gripping element, the element comprising a shape memory material wherein the shape memory material comprises functional porosity.

Preferably the surface or the element is deformable to conform at least in part to the shape of an object gripped thereby to thereby provide enhanced grip

of the object. Preferably the surface of the element is formed of a shape memory material, and in particular a shape memory alloy which may return to a non-deformed condition through a shape memory phase transformation upon heating.

The term shape memory material is used herein to refer to a material which recovers from a deformed shape to a pre-formed, substantially stress-free shape on being subjected to certain predetermined conditions.

Preferably the device comprises a pair of co-operating gripping members, each of which provides a gripping surface whereby an article may be held between the surfaces.

Preferably a coating or an insert of the shape memory alloy is provided on each gripping member to form the respective gripping surface.

The shape memory alloy may be a titanium-nickel alloy, preferably a nominally equiatomic alloy, with a composition of desirably between 48-52% atomic % Nickel Titanium. The alloy preferably comprises functional or residual porosity.

The alloy coating or insert may be applied or attached by brazing, soldering, riveting, sintering or compression fit.

Preferably the device is a surgical needle holder, desirably in the form of forceps.

The invention will be further described for the purposes of illustration only with reference to the following accompanying drawings in which:-

Fig. 1 is a diagrammatic drawing of a surgical needle holder made in accordance with the invention; and

Fig. 2 shows schematically the operation of the jaw inserts.

Referring to Fig. 1, a stainless steel surgical needle holder 10 takes the general form of a pair of forceps. The holder 10 has a pair of jaws 12 movable about a pivot 14. Each jaw 12 has an inner surface 16 in which is provided an insert 18. Each insert 18 provides a gripping surface 20 so that the respective gripping surfaces 20 come into contact with one another when the needle holder is in a closed condition.

Each insert 18 is made from a nominally equiatomic nickel-titanium shape memory alloy, and is formed by a process which will be described hereinafter. The gripping surface 20 provided by the alloy insert 18 is deformable on the application of a force such as may be applied to hold a conventional stainless steel surgical needle 22 in place within the jaws 12 of the needle holder (see Fig. 2B). The inserts 18 thus deform when a needle is gripped enabling a secure and accurate grip to be achieved without damage to the needle itself. The nickel-titanium shape memory alloy has a relatively high coefficient of friction and effectively acts as a sticky material gripping the needle.

The shape memory alloy from which the inserts 18 are formed comprises functional porosity, also known as residual porosity. The functional porosity of the insert allows the device 10 to deform around an article to be gripped such as a needle. This feature in this embodiment has the advantage that it increases the recoverable shape memory deformation from 8% in the prior art cases to about 50%. The functional porosity provides the embodiments described herein with the advantage that the pores allow a greater volume of the insert to be compressed around an object, e.g. a suture needle than would be possible with prior art jaws i.e. jaws that do not comprise functional porosity.

In one embodiment, the shape memory alloy of the inserts 18 are in the martensitic form at room temperature. The compression of the inserts 18 around a needle 22 as shown in Fig. 2 causes the inserts 18 to deform such that they correspond, at least in part, to the shape of the needle 22. The deformation of the inserts 18 around the needle 22 is a plastic deformation and ensures the grip is as accurate as possible, as described above. While not wishing to be restricted to a particular mechanism or theory, it is believed that the deformation of the inserts causes martensitic twinning in the inserts.

The size of the inserts permits several gripping operations to be made before the insert is substantially deformed over its surface. The insert material then requires to be subject to appropriate conditions to cause shape recovery, to return it to its original (undeformed) condition. The nickel-titanium alloy employed in the present example has a martensite to austenite phase transformation temperature occurring between 50°C and 100°C, and its shape memory effect can therefore be realised either by immersion in hot water or by routine autoclave sterilisation.

Thus, when it is desired to return the inserts 18 to their original non-deformed configuration, the inserts 18 can be heated as discussed above to a temperature of between 50°C and 100°C. This causes the inserts 18 to return to their original configuration.

In another embodiment, the inserts are in the austenitic phase at room temperature. The deformation of the inserts around the object utilises the superelastic effect, and the inserts recover their original shape on releasing the object. Again it is not wished to be limited to a particular mechanism, but it is believed that the compression of the inserts causes the creation and twinning of stress induced martensite.

It is believed that the pores provided by the functional porosity provide a means of producing an open, extended network of Ni-Ti bridges that can be easily compressed upon squeezing the inserts around an object e.g. a suture

needle.

In the present examples, the inserts 18 are produced from elemental pure nickel and titanium powders. The powders are mixed in the approximate ratio 50 at % Ni-Ti, cold compacted and subjected to an inert atmosphere (argon) sinter. The resulting sintered compact contains closed porosity, the extent of which can be controlled by variation of the cold compaction pressure and the initial particle size of the nickel and titanium powders. Modification of the theoretical density of the jaw inserts can thus be achieved. The powder process Ni-Ti intermetallic exhibits the shape memory effect, with a martensite to austenite phase transformation temperature occurring between 50°C and 100°C, dependent upon the composition.

The inserts 18 may be attached to the needle holder either by riveting, soldering, sintering or brazing. The present example employs a type of silver solder, namely a silver-copper-zinc-tin alloy supplied by Eutectic Co. Ltd. of Worcestershire, under the name Superflux 1020. The corresponding flux permits the solder to wet the stainless steel of the needle holder 10 relatively easily. To coat the alloy insert, it was first covered in molten flux, then a small quantity of the solder was melted on it. Oxide forming on the surface was scratched through the solder with an appropriate pointed stainless steel instrument. With the alloy insert held at a suitable degree of super-heat, the solder flowed under the oxide film thus lifting it off. The slag was scraped off and fresh flux applied as protection.

When both surfaces had been coated with solder, they were joined and re-heated until they sweated, ensuring that the correct relative positions were retained.

There is thus provided a surgical needle holder which enables a good grip to be obtained without significant likelihood of damage to the needle.

Modifications may be made within the scope of the invention. In particular, a deformable gripping surface may be provided by other materials

than those described, and may be provided on the needle holder in any convenient manner. The invention extends to surgical equipment other than needle holders.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

Claims

1. A biocompatible gripping device for surgical use, the device comprising gripping means having at least one deformable gripping element, the element comprising a shape memory material wherein the shape memory material comprises functional porosity.

2. A biocompatible gripping device according to claim 1 wherein the deformable gripping element is deformable on gripping an article and can be returned to a non-deformed condition after releasing the article.

3. A biocompatible gripping device according to claim 2 wherein the deformable gripping element can be returned to its non-deformed condition on heating.

4. A biocompatible gripping device according to claim 3 wherein the deformable gripping element can return to the non-deformed condition on heating to a temperature of between 50°C and 100°C.

5. A biocompatible gripping device according to claim 1 wherein the shape memory material comprises a shape memory alloy.

6. A biocompatible gripping device according to claim 5 wherein the shape memory alloy is a nominally equitomic alloy.

7. A shape memory alloy according to claim 6 wherein the shape memory alloy is a titanium-nickel alloy.

8. A shape memory alloy according to claim 7 wherein the shape memory alloy is a titanium nickel alloy having substantially 52 atomic % titanium and substantially 48 atomic % nickel.

9. A biocompatible gripping device according to claim 1 wherein the

deformable gripping element is selected from a coating and an insert.

10. A biocompatible gripping device according to claim 8 wherein the deformable gripping element is applied to the gripping means by brazing, soldering, riveting, sintering or compression fit.

11. A biocompatible gripping device according to claim 1 wherein the device comprises a pair of co-operating gripping members, each of which includes a gripping surface whereby at least one of said surfaces is provided by said deformable gripping element.

12. A biocompatible gripping device according to claim 11 wherein each of said gripping surfaces is provided by a respective one of said deformable gripping elements.

13. A biocompatible gripping device according to claim 11 in the form of a surgical needle holder.

14. A biocompatible gripping device according to claim 11 in the form of forceps.

Abstract

Title: **A Biocompatible Gripping Device**

A biocompatible gripping device for surgical use comprises gripping means having at least one deformable gripping element. The element comprises a shape memory material which may comprise functional porosity. The shape memory material may be a shape memory alloy.

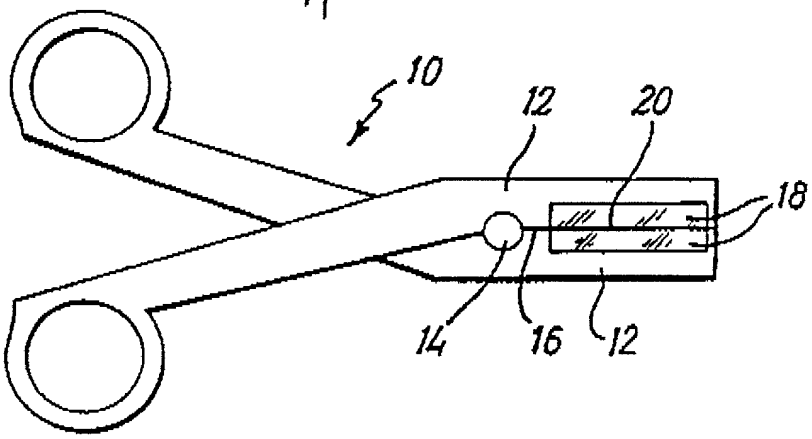

FIG.1

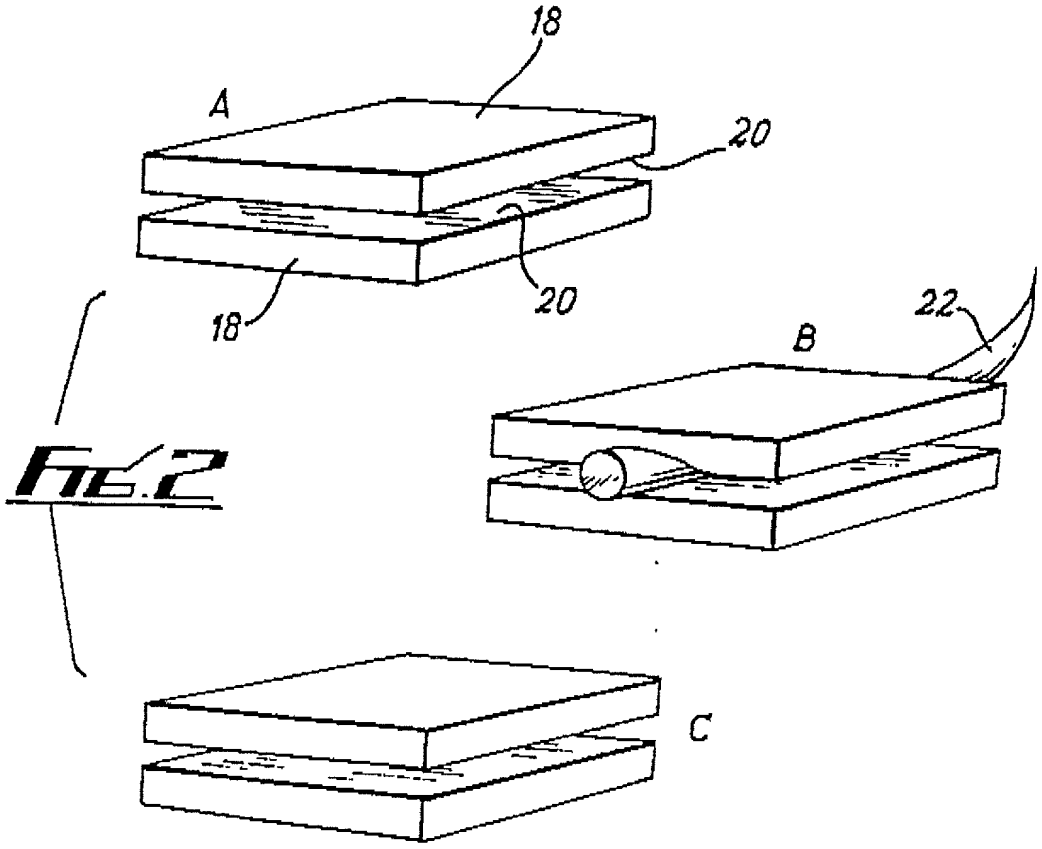

FIG.2